

Remarks

In the Office Action of June 22, 2005, the Examiner objected that Figures 1a, 1b, and 1c show sequences that do not have sequence identifiers. The specification is now amended in the Brief Summary of the Drawings to identify the Sequence ID Numbers of the sequences listed.

Claim 30 is objected to for not reciting an isolated and purified DNA fragment. With the present amendment it is believed that this objection is overcome.

Claim 26 is objected to under 37 CFR 1.75(c) for being of improper dependent form for failing to further limit the subject matter of the previous claim. The Examiner objected that claim 26 does not require our claimed nucleic acid to be of any specific coding sequence, thus broadening the scope of claim 23 on which it depends.

The objection of claim 26 for being of improper dependent form is respectfully traversed. By the very nature of claim 26 being dependent on claim 23 it must include all the limitations of claim 23. Accordingly, this scope of claim 26 can not be broader than the scope of claim 23.

Claims 37-39 are objected to under 37 CFR 1.75 (c) as being of improper dependent form for failing to limit subject matter of the previous claim. The Examiner concluded that the claimed immunogenic fragment defines a polypeptide of any size that will induce an immune

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response and, therefore, broadens the scope of claim 34, which requires the polypeptide to be at least 40 amino acids in length. The same objection is recited for claims 43-45, with respect to claim 40.

For the reason set forth above with respect to claim 26, Applicants respectfully traverse the objection to claims 37-39 and 43-45. These claims depend, respectively, on claim 34 and claim 40 and must, therefore, include all limitations of those claims, and therefore, for example, must be at least 70 amino acids in length.

Claim 46 is objected to for being dependent on multiple claims. With the present amendment to claim 46, it is believed that this basis for this objection is overcome. The various embodiments have now been recited in new claims 57 and 58.

Claim 49 is objected to for being of improper Markush format. It is believed that with the present amendment to claim 49, the basis for this objection has been overcome.

Claim 51 is objected to for being of improper dependent form for depending on claims simultaneously. Claim 51 is now canceled without prejudice or disclaimer of the subject matter thereof.

Claims 52-54 are objected to for being of improper dependent form. Claims 52-54 are now amended to recite methods for detecting *Helicobacter felis* and, for that reason, it is believed that this objection is overcome. Furthermore, the objection to claim 53 for broadening the scope of the claims it depends is respectfully traversed as it necessarily includes all of the limitations of the independent claim.

Claims 46-49 stand rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The claims are said to contain subject matter not described in the specification as to enable one of skill in the art to make and/or use the invention. Claims 46-49 are said to be directed to a vaccine comprising fragments of nucleic acid that are 40 nucleotides in length as well as homologous nucleic acid sequences and may be of a size larger than 40 nucleotides in length but they are not required to encode any specific sequence as long as the polypeptide is immunogenic. The specification is objected to for not providing working examples of vaccines to enable the claimed invention.

Claims 46-49 are now amended to be directed to immunogenic compositions, which are believed to be well within the skill of the art at the time this application was filed.

Claim 23 is objected to for using the expression "such as," for rendering the claims indefinite, and claim 26 is objected to for depending on claim 23 wherein there is not said to be provided antecedent basis for the recited X and Y subunit polypeptides.

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It is respectfully submitted that the objections to claim 23 and 26 are overcome with the present amendments.

Claims 34 and 35-39 that depend on it stand rejected under 35 U.S.C. 112, second paragraph, for reciting the limitation "ureaseXY" in reference to the term "urease X." There is said to be insufficient antecedent basis for the limitation "ureaseXY" in the claim. For the same reasons claims 40 and 41-45 stand rejected with respect to the term "urease Y."

It is respectfully submitted that with the present amendments to claims 34, 37-40 and 44, and the cancellation of claims 35, 36, 41-43 and 45, this objection is overcome.

Claims 23-50 and 52-54 stand rejected under 35 U.S.C. 112, second paragraph, for being indefinite. All of the claims recite the term "homologous" or "homology," but what this structurally means is said to be unclear.

The rejection of claims 23-50 and 52-54 for referring to homologous sequences is respectfully traversed. In addition to the discussion of homology in the specification, Applicant's have demonstrated homology among various species of *Helicobacter felis*. This is reported in the figures, at the top of Figure 1a. It is noted that specific homology within the group of isolates is 94% in all cases except isolate 390, which is 85%. Accordingly, the degrees of homology claimed are supported in the Specification. For comparison, the *Helicobacter felis* comp isolate, which is broadly available, provided only 67% homology in the urease X and urease Y subunits,

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as did *H.pylori* com and *H.heilmannii* with 68%. It is respectfully submitted that the ordinary practitioner with the information provided in the Specification and the knowledge in the art at the time this application was filed could easily identify *Helicobacter felis* sequences having the required 85% or 94% homology and further determine their immunogenic effects without undue experimentation. It is respectfully submitted that the invention claimed is fully enabled. As claimed, the sequences must have a certain percentage of homology with identified sequences, which can easily be determined, and have a length of at least 70 nucleotides. It is believed that this information, supported by the sequence information provided by the Applicants, fully enables the skilled practitioner to practice the present invention.

Claims 23-50 and 52-54 stand rejected under C.F.R. 102(b) for being anticipated by Labigne et al (U.S. Patent 5,843,460). This reference is said to disclose the instantly claimed invention directed to an isolated nucleic acid of *Helicobacter felis* urease encoding at least an immunogenic fragment of one of the subunits wherein the immunogenic fragment is encoded by a sequence of at least 40 nucleotides of length and shares 100% identity with certain nucleic acids of Sequence ID NO: 1, as well as encoding a functional homolog of the claimed *Helicobacter felis* urease, as it shares 85% sequence identity with Sequence ID NO: 3. The Examiner stated that while Labigne et al does not refer to the *Helicobacter felis* urease that comprises two subunits, as urease subunit X and Y, the disclosed *Helicobacter felis* urease subunits anticipate the claimed invention directed to *Helicobacter felis* urease homologs that share a nucleic acid sequence with at least 85, 90, 94 or 97% sequence homology with SEQ ID NO:1.

With the present amendments it is believed that the rejection for anticipation over Labigne et al is overcome. Claim 23 is now amended to recite that the immunogenic fragment must have a length of 70 nucleotides. Support for this limitation is found in the Specification on page 4, in paragraph 3.

It is further believed that the sequences disclosed in Labigne et al do not anticipate Applicants' claims as the fragments do not appear to be both 85% homologous to the claimed sequences and have a length of 40 amino acids. Should the review on behalf of Applicants be in error, it is requested that the Examiner point out the sequence identity that meets these limitations.

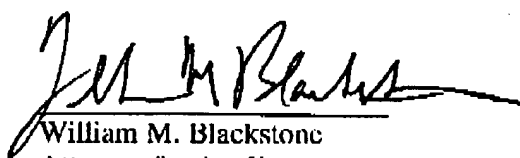
Applicants respectfully submit that the claimed nucleic acid molecules and peptides according to the present invention are neither anticipated nor obvious in view of the cited art with the present amendments. It is believed that claims 23, 26, 28, 30-34, 37-40, 44, 46-50, and 52-58 are in condition for allowance. Favorable action is solicited.

Should the Examiner consider that a conference would be helpful in advancing the prosecution of the application she is invited to telephone Applicants' attorney at the number below.

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If necessary, the Commissioner is hereby authorized in this concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17.

Respectfully submitted,



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